

ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1

12

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 02/14/2020		2. CONTRACT NO. (If any) HHSO100201600005I		6. SHIP TO:	
3. ORDER NO. 75A50120F33009		4. REQUISITION/REFERENCE NO. OS253976		a. NAME OF CONSIGNEE HHS/OS/ASPR	
5. ISSUING OFFICE (Address correspondence to) ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201				b. STREET ADDRESS 200 C St SW WASHINGTON DC 20201	
				c. CITY WASHINGTON	e. ZIP CODE 20201
7. TO: DANIEL				f. SHIP VIA	
a. NAME OF CONTRACTOR PROTEIN SCIENCES CORPORATION 373074				8. TYPE OF ORDER	
b. COMPANY NAME				<input type="checkbox"/> a. PURCHASE <input checked="" type="checkbox"/> b. DELIVERY	
c. STREET ADDRESS PROTEIN SCIENCES CORPORATION 1 1000 RESEARCH PKWY				REFERENCE YOUR: Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.	
d. CITY MERIDEN		e. STATE CT	f. ZIP CODE 064507149	Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.	
9. ACCOUNTING AND APPROPRIATION DATA 2020.1991078.26049				10. REQUISITIONING OFFICE BARDA	

11. BUSINESS CLASSIFICATION (Check appropriate box(es))				12. F.O.B. POINT	
<input checked="" type="checkbox"/> a. SMALL <input type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED VETERAN-OWNED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM <input type="checkbox"/> h. EDWOSB					
13. PLACE OF		14. GOVERNMENT B/L NO.		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 06/14/2021	
a. INSPECTION Destination	b. ACCEPTANCE Destination			16. DISCOUNT TERMS	

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number: 06-1098847 DUNS Number: 109124933 ASPR-20-00906 -- Protein Sciences Corporation manufacture of master working seed lot research lots and laboratory testing assays for 2019 nCoV under contract HHSO100201600005I Appr. Yr.: 2020 CAN: 1991078 Object Class: 26049 Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:						
	a. NAME PSC/FMS						\$849,451.46
	b. STREET ADDRESS (or P.O. Box) PSC_invoices@psc.hhs.gov						
c. CITY		d. STATE	e. ZIP CODE		\$849,451.46		17(i) GRAND TOTAL

22. UNITED STATES OF AMERICA BY (Signature)

Wendell Conyers-S

Digitally signed by Wendell Conyers-S
Date: 2020.02.14 15:44:15 -05'00'

23. NAME (Typed)
WENDELL CONYERS
TITLE: CONTRACTING/ORDERING OFFICER

ORDER FOR SUPPLIES OR SERVICES

PAGE NO

SCHEDULE - CONTINUATION

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IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER

CONTRACT NO.

ORDER NO.

02/14/2020

HHS0100201600005I

75A50120F33009

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Period of Performance: 08/16/2016 to 06/14/2021					
1	ASPR-20-00906 -- CLIN 1801B Vaccine Research Lots (qty 2) - 2019 nCoV 1 - rapid research grade process and material 1- cGMP ready process				785,165.46	
2	ASPR-20-00906 -- CLIN 1801C Laboratory Testing Assay - 2019 nCoV				64,286.00	
3	ASPR-20-00906 --Protein Sciences Corporation (PSC), has agreed to cost share with the USG. PSC will Manufacture Master/Working virus seeds lot(s) for nCoV vaccine (\$148,647.00). Amount: \$0.00 (Option Line Item) (Not Separately Priced)	1	EA		0.00	
The total amount of award: \$849,451.46. The obligation for this award is shown in box 17(i).						
TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))						\$849,451.46

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS/DIQ

B.2. Contract Line Item Numbers (CLINs) and Pricing:

The Contractor shall be reimbursed by the Government in an amount not less than a total of \$500,000 (minimum) and no more than a total of \$610,028,694 (maximum) if all optional CLINs are exercised.

The prices set forth in this ARTICLE B.2. will cover the Base Period August 22, 2016 through August 21, 2019, Option Period I – August 22, 2019 through August 21, 2020 and Option Period II August 22, 2020 through August 21, 2021. Upon delivery and acceptance of the item(s) described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit prices (s) set forth below. Contractors shall provide the following items for the manufacturing, testing, packaging, delivery, storage and disposal of influenza MCM products. **Add additional pricing to cover requirements in response to a HHS designated Public Health Emergency.**

The following CLINs are added effective February 12, 2020 through August 21, 2020

OPTION 1: February 12, 2020 through August 21, 2020

CLIN	SUPPLIES/ SERVICES	UNIT	QUANTITY	UNIT PRICE	TOTAL EXTENDED PRICE
1801A	cGMP Vaccine Master and Working Seed Lot	Lot	TBD	\$ 148,647.00	\$
1801B	Vaccine Research Lot(s)	Lot	TBD	\$	\$
1801C	cGMP Vaccine Investigational Lot(s)	Lot	TBD	\$ 450,204.00	\$
1801D	cGMP Vaccine Commercial Scale Bulk Lot(s)	Lot	TBD	\$ 2,146,389.00	\$

***Pricing is based on current Option 1 PSC pricing for flu and are subject to changes at time of award of Coronavirus activities task order (s).**

OPTION 2: August 22, 2020 through August 21, 2021

CLIN	SUPPLIES/ SERVICES	UNIT	QUANTITY	UNIT PRICE	TOTAL EXTENDED PRICE
3401A	cGMP Vaccine Master and Working Seed Lot	Lot	TBD	\$ 153,106.00	\$
3401B	Vaccine Research Lot(s)	Lot	TBD	\$	\$
3401C	cGMP Vaccine Investigational Lot(s)	Lot	TBD	\$ 463,710.00	\$
3401D	cGMP Vaccine Commercial Scale Bulk Lot(s)	Lot	TBD	\$ 2,210,781.00	\$

***Pricing is based on current Option 2 PSC pricing for flu and are subject to changes at time of award of Coronavirus activities task order (s).**

A.1 Background

An outbreak of respiratory illness caused by a novel (new) coronavirus (named "COVID-19") that was first detected in Wuhan City, Hubei Province, China continues to expand. Chinese health officials have reported thousands of infections with COVID-19 in China, with the virus reportedly spreading from person-to-person in many parts of that country. Infections with COVID-19, most of them associated with travel from Wuhan, also are

being reported in a growing number of international locations, including the United States. The United States reported the first confirmed instance of person-to-person spread with this virus on January 30, 2020.

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared the outbreak a “public health emergency of international concern” (PHEIC). On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nation’s healthcare community in responding to COVID-19.

As part of HHS preparedness and response activities, HHS has requested PSC to submit a Proposal to produce a Working Virus Bank derived from 2019-CoV and a Vaccine Research Lot in preparation for possible CoV vaccine production.

Protein Sciences Corporation (PSC), a Sanofi company, produces the only FDA licensed recombinant influenza vaccine, Flublok®, and is proud to have worked with BARDA for influenza pandemic preparedness since 2009. With the support of NIH/NIAID/DMID grant N01-AI-30023, we produced recombinant SARS-associated coronavirus (SARS-CoV) S glycoprotein (spike protein). Two recombinant proteins were produced: his-tagged full-length spike protein and the spike protein ecto-domain only (delta-TM). Both forms produced neutralizing antibodies in mice, (Vaccine 24 (2006) 3624–3631); the delta-TM protein also provided partial protection in ferret challenge studies. Our experience with SARS-CoV informs this COVID-19 proposal.

A.1.1 Scope of Work

BARDA Requirement

HHS requires:

- Working Virus Bank (WVB) for 2019 Novel Coronavirus (COVID-19), under CLIN 1801A, cGMP Vaccine Master and Working Seed Lot
- Vaccine Research Lot(s) under CLIN 1801B produced from the WVB produced in CLIN 1801A
- Analytical laboratory testing and assays under CLIN 1101 on the Research Lot(s) produced under CLIN 1801B

The proposed site for this work is our Meriden, CT facility. This facility is licensed for and is used for the commercial production of Flublok® seasonal influenza vaccine.

Independently and not as an agent of the U.S. Government (USG), PSC, a Sanofi company, will furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to in support of this RTOR.

A.1.2 Scope of Work for CLIN 1801A – cGMP Vaccine Master and Working Seed Lot

As a service to the USG (HHS/BARDA), free of charge and exclusive to any forthcoming Task Order associated with this RTOR, PSC will produce a cGMP Working Virus Bank (WVB). This WVB is solely to be used for the production of recombinant nCoV vaccine using the sequence agreed to with BARDA.

We utilize a platform manufacturing technology based on the baculovirus expression vector system (BEVS) for the expression of recombinant proteins in insect cells. In this system, the gene encoding the target protein is inserted into our plasmid vector and transferred into the baculovirus genome through homologous recombination.

The difference of our BEVS virus banking system from the egg-based vaccine manufacturing, is that the “Master Parent Linear Baculovirus Bank” without a gene insert is interpreted by the FDA to be the Master Virus Bank (MVB), and the new recombinant virus bank containing the target gene insert for expression is a Working Virus Bank (WVB). Therefore, we interpret that the requirement for producing Master and Working Seed Lot is equivalent to producing the WVB in our BEVS manufacturing system.

The cloning of the nCoV gene will use synthesized deoxyribonucleic acid (DNA) corresponding to the agreed upon

sequence. After the homologous recombination the mixture of recombinant baculoviruses is diluted and plaque purified. Individual recombinant baculoviruses are selected for expansion. Individual plaques are picked and scaled up to passage 2 (P2). The recombinant viruses are screened by PCR to ensure that the full-length rHA gene is present and by Western blot for confirmation of rHA protein expression. Recombinant viruses that pass these initial criteria are scaled to a passage 3 (P3) WVB. The P3 WVB is the raw material that is transferred to the cGMP facility for freeze-down and subsequent scale-up for production. A typical freeze-down yields 64 WVB vials (1.5 mL each). These are stored in monitored liquid nitrogen tanks; in a QA-controlled, secured area. The cGMP P3 WVB is tested for release, see **Table A.1.2**.

Table A.1.2: Testing and acceptance criteria for Working Virus Bank

Test	Method	Acceptance Criteria
Sterility ¹	Direct Inoculation	No bacterial or fungal contamination observed
Potency ²	Virus Titer (plaque assay)	$\geq 1.0 \times 10^7$ plaque forming units per ml
Protein Identity	Western Blot	Identity confirmed
Adventitious agents	3-Cell In Vitro WuXi AppTec C21189	No adventitious agents detected in MRC-5, VERO, and BHK-21 cells (CPE and non-CPE)
DNA Identity	Restriction and Southern Blot	Gene inserted correctly
	DNA sequencing	Correct DNA sequence confirmed
	PCR	Identity confirmed
¹ Sterility is performed pre and post Freeze		
² Potency is performed pre-freeze, perform and report		

Antibody Reagents: Antibodies will be required to verify protein identity and track expression during CLIN1801A. PSC will source commercially available anti-CoV antibodies and well as those available within the Sanofi network and screen antibodies to determine suitability for use in Western blotting. We will develop antibodies using purified recombinant protein if necessary. Reagents used for release of the GMP WVB will be qualified for that use.

For CLIN 1801A, PSC will:

- Manufacture Master/Working virus seeds lot(s) for nCoV vaccine
 - Using the same facilities, systems, equipment, processes and testing as those described and referenced in the BLA of FDA-licensed influenza vaccine Flublok®, according to current Good Manufacturing Practices (cGMP) as applicable and store at appropriate conditions during lot release testing.
 - Using the gene sequence as specified by CDC/BARDA.
 - Provide a Certificates of Analysis and Compliance
- Store the WVB according to FDA cGMP guidelines, add manufactured WVB lot to ongoing inventory reports and controlled storage.
- Provide reports including, at minimum, the information identified in Section F of contract HHSO100201600005I.

Deviation from base contract technical proposal: None

A.1.3 CLIN 1801B – Vaccine Research Lot(s)

The P3 WVB(s) produced in CLIN 1801A will be used for downstream process development and the production of small-scale (up to 40L of culture) research lot(s). In order to provide purified protein for study as soon as possible and to mitigate the risks associated with undetermined methods for purifying nCoV spike protein; we propose a 2-tiered development approach:

- **Tier 1 – Rapid Research-Grade Process and Material**

- Will leverage existing SARS process
- May use processes and materials not carried forward to GMP-ready process
- Will begin assay and reagent work
- Develop preliminary stability data
- Provide purified protein for characterization studies, animal studies and reagent/analytical development as quickly as possible
- **Tier 2 – cGMP-Ready Process**
 - Continue to develop an Industrial Process and analytics for GMP manufacturing
 - Characterize protein
 - Conduct stability study
 - Provide purified protein for non-clinical use

Tier 1 – Rapid Research-Grade Process and Material

We will conduct small-scale scouting experiments to begin understanding the behavior of the nCoV spike protein. General purification includes centrifugation of the cell culture, extraction of cell-associated proteins, clarification, purification of the target protein, concentration, buffer exchange and 0.2 µm filtration, see **Table A.1.3-a**.

Table A.1.3-a: General DSP Steps

Process Step	Purpose
Centrifugation	Separation of cells and medium. Full-length spike protein is expected to pellet with the cells, truncated variants may be in the cell culture medium.
Extraction	Expected to be required only for full-length spike protein: Extraction and solubilization of the protein from the cell membranes
Clarification	Clarification of the cell extract or medium by removal of particulates and cell debris
Primary-Capture Chromatography	Initial chromatographic steps to remove impurities
Secondary-Polishing Chromatography	Final orthogonal chromatography steps to improve purity
Ultrafiltration	Concentration of target protein and buffer exchange
Bulk Filtration	Final filtration through a 0.2-micron filter to ensure a low bioburden bulk

If a full-length spike protein is expressed, we expect spike protein to reside in the *expresSF+* cell membrane; therefore, these experiments will include extraction from the cell membrane. If a truncated variant is selected; then extraction development is unlikely. We expect development efforts to focus on:

- Extraction (if required)
- Primary and Secondary chromatography and
- Ultrafiltration

Process performance parameters will be monitored during development, initially with assays available and later with specialized assays. SDS-PAGE, Western blotting and BCA will be used in Tier 1 to assess yield, purity and protein size/integrity.

In Tier 1 development, we may use materials (e.g. chromatography resins, buffers, surfactants, ultra-filters) that are not in the Flublok® licensed process, including affinity resins. These materials may not be in the final GMP-

ready process. Once basic steps are defined, we will conduct process experiments at the 1L and 4L bioreactor scales. A brief stability characterization study (1 month) will be conducted in Tier 1 using the available appropriate tests.

The goal of Tier 1 work will be to provide purified nCoV recombinant protein suitable for characterization studies, animal studies and reagent/analytical development as quickly as possible.

Analytical Development

Antibodies will be required to verify protein identity and track purification during CLIN 1801B. Based on our experience with SARS-CoV spike protein, we anticipate the development of an ELISA potency assay, which will require CoV antibodies. PSC will source commercially available anti-CoV antibodies and well as those available within the Sanofi network and screen antibodies to determine suitability for use in Western blotting and ELISA. We will develop antibodies using purified recombinant protein if necessary. Reagents and assays used for GMP will be qualified for that use under a separate task order.

During Tier 1, we will begin to examine the analytical tools intended for protein characterization and those which may be used for drug substance release; see **Table A.1.3-b**. Assay work is expected to continue into Tier 2. This work will be done in our Manufacturing Technology development laboratories.

Table A.1.3-b: Assays for Initial Examination. Specifications are TBD.

Test	Method	Comments
Potential release tests		
Total Protein Content	BCA	No development anticipated
Purity	SDS-PAGE / Densitometry	Will require suitable antibody
Identity	Western blot or ELISA signal	Will require suitable antibody ELISA will require assay development
Host Cell Protein	Western Blot	Will require assessment, may require suitable antibody
Potency	ELISA (SARS SOP QT0104 will be used as a starting point)	Will require suitable antibody and assay development.
Total DNA	Picogreen	No development anticipated
Size Analysis	U/HPLC-SEC and/or DLS	HPLC-SEC: TBD DLS: No development anticipated
Appearance	Visual inspection	No development anticipated
Microbial Enumeration		No development anticipated
Endotoxin	LAL Gel Clot	No development anticipated
pH	Potentiometry	No development anticipated
Infectious Baculovirus	Titer	No development anticipated

Test	Method	Comments
Characterization only test		
Deglycosylation	Enzyme treatment and SDS-PAGE	Characterization test No development anticipated Detects presence of glycosylation

Tier 2 – cGMP-Ready Process

The process will be refined and scaled-up in our Manufacturing Technology laboratory to the 10L and 40L bioreactor scales. We will verify that the process consistently produces protein of acceptable quantity and quality. These larger scales are sufficiently predictive of process performance to allow technology transfer to cGMP manufacturing.

Reagent and assay development initiated in Tier 1 is expected to continue into Tier 2. During Tier 2 we expect to develop sufficient data to support the creation of release specifications and the required assay documentation. In-process yields will be assessed by total protein (BCA), SDS-PAGE/Western blot and ELISA when available.

Characterization Testing

The proposed product characterization for the Tier 2 research lot (**Table A.1.3-c**), will allow an assessment of product quality, readiness for cGMP production and suitability of use in non-clinical studies. These studies will be performed in by our Manufacturing Technology group.

Table A.1.3-c: Proposed Product Characterization Testing for rCoV Research Lot(s). Acceptance Criteria are TBD.

Parameters/Assays Performed	Method
Purity	SDS-PAGE / Densitometry
Total Protein Content	BCA
Potency	ELISA
Size Analysis	UPLC-SEC and/or DLS
Deglycosylation	Enzyme treatment and SDS-PAGE
Total DNA Content	Picogreen
Host Cell Protein	Western Blot
Endotoxin	LAL Assay
Infectious Baculovirus	Titer
Microbial Enumeration	

Process transfer for manufacturing, GMP documentation, generation of release specifications, and GMP qualification of reagents and assays will be done under a separate task order.

Deliverables: For CLIN 1801B, we will:

- Prepare research lot(s) as directed by HHS as specified in the task order.
- Provide data derived from the manufacturing process.

- Provide reports including, at minimum, the information identified in Section F of contract HHSO100201600005I.
- We will issue a Final Report after completion of activities relating to Master and Working Virus Seed Lot (CLIN 1801A) and Research Lot (CLIN 1801B) and will include activities up to release of the WVB and completion of development lot testing (CLIN 1801B).

Deviations from base contract technical proposal: The base contract technical proposal was developed to utilize the licensed Flublok design space; which is not appropriate for nCoV spike protein. To the greatest extent possible we will adhere to licensed materials, procedures and processes.

A.1.4 CLIN 1101 – Analytical Laboratory Testing/Assays

Stability

We propose the following stability program for the research lot. We will discuss the details of the stability program with HHS. Research lots will be placed on real-time and accelerated stability. Stability storage temperatures and containers are to be determined. The study will be conducted by our Manufacturing Technology group. The proposed schedule is shown in **Table A.1.4**.

Table A.1.4: Proposed Stability Schedule. X indicates time point is performed; acceptance criteria are to be determined.

Studies	Time Point								
	Day 0	1wk	2wk	1 m	1.5 m	3m	6m	9m	12m
Real Time	X	-	X	X	-	X	X	X	X
Accelerated	X	X	X	X	X	X	-	-	-

At each time point, we will assess:

- Potency by ELISA,
- Size by HPLC-SEC and/or DLS,
- Protein integrity and conformation by SDS-PAGE/Western Blot (reducing and non-reducing conditions).

Deliverables: For CLIN 1101, we will:

- Conduct laboratory testing/assay as required by HHS and specified in the task order
- Provide reports including, at minimum, the information identified in Section F of contract HHSO100201600005I.

Deviation from base contract technical proposal: The CLIN 1101 activities in the base contract technical proposal were based on the studies performed for the Flublok® influenza vaccine; some of which are not appropriate for nCoV spike protein. To the greatest extent possible we will adhere to the tests and study protocols used for Flublok®.

A. DELIVERY SCHEDULE

A.1 Schedule for cGMP Vaccine Master and Working Seed Lot

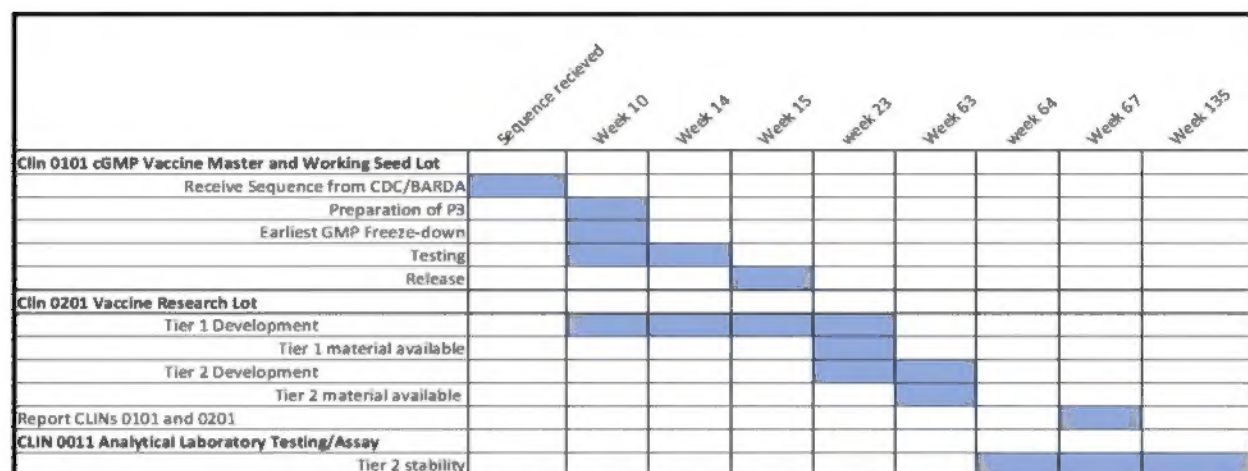
CLIN 1801A GMP freeze-down and WVB release may be delayed to accommodate commercial influenza vaccine production; however, such delay will not impact development work under CLIN 1801B. If there are no delays, we

expect freeze-down 11 weeks after agreement on target sequence and release by week 16.

A.2 Delivery schedule for Vaccine Research Lot(s)

Work under CLIN 1801B is early-stage development; therefore, this schedule may shift. We will adhere to this schedule to the greatest extent possible and will inform BARDA of our progress and anticipated delays. We expect to have Tier 1 material available 24 weeks after agreement on target sequence and Tier 2 material after 64 weeks.

A.3 Gantt chart including at a minimum the major tasks, critical subtasks, and deliverables



A.4 Business Proposal

Below is our Business Proposal for activities as we understand them today quoted as a firm fixed price, with the exception of CLIN 1801A which will be performed as service to the USG (HHS/BARDA), free of charge and exclusive to any forthcoming Task Order associated with this RTOR. Should any of the project requirements/deliverables deviate from the items noted above in our Technical Proposal, we would then initiate a request for task order modification. For a list of Key Assumptions and Clarifications regarding this Proposal, please see Appendix B.1 -Key Assumptions and Clarifications.

PSC will furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to manufacture 1 cGMP Vaccine Master and Working Seed Lot, 1 Vaccine Research Lot, and conduct all specified Laboratory Testing on each lot. The WVB produced under CLIN 1801A will be at Sanofi's own cost See **Table B.4-a** for proposed pricing of CLIN 1801A; **Table B.4-b** for propose pricing of CLINs, 1801B, 1101, and 1601; and **Table B.4-c** for proposed pricing on Optional CLINs.

Table B.4-a Proposed Pricing of CLIN 1801A

CLIN	SUPPLIES/ SERVICES	UNIT	QTY	TOTAL COST	COST SHARE PSC 100%	COST SHARE BARDA 0%
1801A	cGMP Vaccine Master and Working Seed Lot	LOT	1	\$148,647.00	\$148,647.00	\$0.00

Table B.4-b Proposed Pricing of CLINs 1801B, 1101, and 1601

CLIN	SUPPLIES/ SERVICES	UNIT	QTY	UNIT PRICE	TOTAL EXPECTED PRICE
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1801B	Vaccine Research Lot*	LOT	1	\$785,165.46	\$785,165.46
1801C	Laboratory Testing/Assay**	Each	1 Study	\$64,286.00	\$64,286.00
1601	Additional Reporting	Report	N/A	NSP	NSP

* As described in our technical proposal section A.1.3 CLIN1801B includes the manufacture of **Tier 1 – Rapid Research-Grade Process and Material and Tier 2 – cGMP-Ready Process**

**1101 for Stability Testing only

Table B.4-c Proposed Pricing for Optional CLINs

CLIN	SUPPLIES/ SERVICES	UNIT	QTY	UNIT PRICE	TOTAL EXPECTED PRICE
1801C	cGMP Investigational Lot(s)	LOT	TBD	TBD	TBD
0601A	Formulation and Filling: Antigen Single Dose Vials	EACH	TBD	TBD	TBD

APPENDIX B.1 - KEY ASSUMPTIONS AND CLARIFICATIONS

KEY ASSUMPTIONS AND CLARIFICATIONS

Regarding our proposal to this Revised Request for Task Order Response# 2020-002, PSC makes the following Key Assumptions and Clarifications:

- This Proposal is in direct response to Revised RTOR-2020-002 and the deliverables set forth under CLIN 1801A - cGMP Vaccine Master/Working Seed Lot(s), CLIN 1801B - Vaccine Research Lot(s), CLIN 1101 Analytical Laboratory Testing/ Assay(s) Contract HHSO100201600005I.
- Task Order is issued by HHS no later than 21 February 2020 in order to meet projected timelines. This is to allow internal resource and facility allocation and commitment to assure we can meet the specified delivery dates in the project plan.
- Acceptance of material created under this contract will be made by duly authorized USG representatives (the CO or the duly authorized representative who for purposes of this contract will be the TOCO) and they will notify PSC of acceptance or rejection within 5 business days. Absent formal notification, acceptance will be presumed.
- HHS will not seek to transfer the materials to another manufacturer without considering the regulatory and legal issues surrounding the sharing of manufactured drug product materials produced under this RTOR.
- Invoice payment is expected per CLIN upon completion of deliverables specified in separate or combined task orders.
- Timing of distribution of genetic sequence(s) will be coordinated by BARDA with CDC and will reflect the start of CLIN 1801A.
- PSC understands that the USG shall grant an irrevocable worldwide non-exclusive sublicensable royalty-free license to use for any purpose any and all improvements and intellectual property that result from the USG or USG's collaborator's use of the material provided hereunder by PSC

and affiliates to the USG.

- No products manufactured and stored under this contract will be moved from the manufacturer's facilities unless and until a Material Transfer Authorization is mutually agreed to and implemented.